

REMARKS

The above-identified application has been carefully reviewed in light of the Examiner's communication mailed March 25, 2004.

Claims 1 and 20 have been amended to more clearly identifying the first and second polyanionic component portions. In addition, claim 27 has been amended to correct a typographical error. These amendments are fully supported by the present specification, for example, page 3, line 32 and page 4, line 14.

In view of the amendments to claims 1 and 20, applicant submits that the present claims satisfy the requirements of 35 U.S.C. 112, first paragraph. Therefore, applicant respectfully requests that the rejection of the present claims, and in particular claims 1 to 5, 7, 9 to 25 and 31 to 34, based upon this statutory provision be withdrawn.

Claims 1 to 34 have been rejected under 35 U.S.C. 103 as being unpatentable over Dikstein. Applicant traverses this rejection as it pertains to the present claims 1 to 34.

The present claims are directed to ophthalmic compositions comprising an ophthalmically acceptable carrier component and a polyanionic component.

In independent claim 1, the polyanionic component includes a first polyanionic component portion having a first molecular weight and a second polyanionic component portion having a second, different molecular weight. The first and second polyanionic component portions are each present in an amount effective to provide lubrication to an eye when the composition is administered to the eye.

In independent claim 20, the polyanionic component includes at least two polyanionic component portions. Each of the at least two polyanionic component portion has a different molecular weight and is present in an amount of at least about 0.1% (w/v) of the composition.

In the above independent claims, the first and second polyanionic component portions (claim 1) and the at least two

polyanionic component portions (claim 20) are selected from anionic cellulosic derivatives; anionic homopolymers and copolymers comprising units of one or more of acrylic acid, methacrylic acid, metal acrylates and metal methacrylates; and mixtures thereof.

The present compositions provide effective lubrication to eyes, for example, eyes suffering from "dry eye" syndrome. The present compositions are relatively straightforward, can be easily and cost effectively manufactured and can be used much like prior art eye lubricating materials. Importantly, the present compositions include combinations of different molecular weight polyanionic materials and preferably provide relatively long lasting, effective eye lubrication, for example, without the need for very frequent readministration or replenishment to the eye, and advantageously without being unduly disruptive to clear vision from the eye being treated.

Dikstein discloses isotonic humectant eyedrops which have non-Newtonian rheological properties, simulating the rheological behavior of human tears. Dikstein discloses that the eye drops include the essential components of water, an anionic polymer having a molecular weight in the 500,000 to about 4,000,000 range and a low molecular weight humectant polyol at a concentration of about isotonicity or slightly above. In the examples, Dikstein discloses combinations of glycerol together with sodium hyaluronate, polyacrylate, and polyacrylate and sodium hyaluronate.

Dikstein does not disclose, teach or suggest the present invention. For example, Dikstein does not disclose, teach or even suggest an ophthalmic composition comprising an ophthalmically acceptable carrier component and a polyanionic component including a first polyanionic component portion and a second polyanionic component portion, or at least two polyanionic component portions, with each of the polyanionic component portions having a different molecular weight and being selected from anionic cellulosic derivatives; anionic homopolymers and copolymers comprising units of at least one of acrylic acid, methacrylic acid, metal acrylates and metal methacrylates; and mixtures thereof, as recited in the

present claims.

In addition, none of the examples of Dikstein disclose or even suggest a composition as recited in the present claims. For example, in each of the examples of Dikstein only one ingredient, a polyacrylate, is identified which is somewhat similar to a material which may be included in the present compositions. In contrast, as noted above, each of the present claims recites a first and second polyanionic component portions or at least two polyanionic component portions of one or more certain defined polyanionic components, with each of the portions having a different molecular weight.

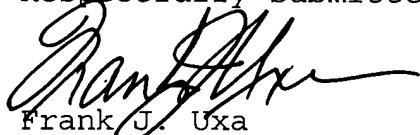
Clearly, Dikstein is deficient with regard to the present claims. Only after knowing of the above-identified application would one of ordinary skill in the art modify and extend the teachings of Dikstein to include first and second polyanionic component portions or at least two polyanionic component portions of the presently defined certain polyanionic components with each component having a different molecular weight, as recited in the present claims, and obtain a substantial and important advantages achieved by applicant. Dikstein discloses compositions including only a single portion of a polyanionic component similar to that disclosed in the above-identified application and, thus, actually teaches away from compositions including first and second portions or at least two portions of such a polyanionic component having different molecular weights, as recited in the present claims.

In view of the above, applicant submits that the present claims, that is claims 1 to 34, are unobvious from and patentable over Dikstein under 35 U.S.C. 103 (a).

Each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art, taken singly or in any combination, discloses, teaches or even suggests the compositions including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In conclusion, applicant has shown that the present claims satisfy the requirements of 35 U.S.C. 112, first paragraph, and are unobvious from and patentable over the prior art under 35 U.S.C. 103(a). Therefore, applicant submits that claims 1 to 34, are allowable and respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Respectfully submitted,



Frank J. Uxa  
Attorney for Applicant  
Reg. No. 25,612  
4 Venture, Suite 300  
Irvine, CA 92618  
(949) 450-1750  
Facsimile (949) 450-1764

FJUxa/ac